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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,188	04/05/2000	David J. Hammond	18242-507 (VI-7)	6857

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/09/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/543,188	HAMMOND ET AL.
	Examiner	Art Unit
	Zachariah Lucas	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 July 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-75 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) 40 is/are objected to.

8) Claim(s) 1-75 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6)  Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-29, and 39 drawn to ligands of the prion protein and compositions thereof, classified in class 436, subclass 543.
  - II. Claims 40-44, 56-66, and 67-71, drawn to methods of detecting prions in samples by detecting prion/ligand complexes, classified in class 436, subclass 86. (Amino resins will be considered as polypeptide ligands for prosecution purposes absent reasons to distinguish them).
  - III. Claims 45-50, drawn to methods of removing prions from samples by removing prion/ligand complexes from the samples, classified in class 424, subclass 344.
  - IV. Claims 51-55, drawn to methods of treating prion-associated pathologies by administering prion ligands to a subject, classified in class 514, subclass 1.
  - V. Claims 30-38, drawn to methods of identifying ligands to prion proteins.
2. For each of inventions I-V above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-V and one of inventions (A)-(F)
  - (A) the ligand is a nucleic acid
  - (C) the ligand is a polypeptide
  - (D) the ligand is carbohydrate
  - (E) the ligand is a lipid
  - (F) the ligand is an inorganic molecule

The list above is not meant to all-inclusive, it merely recites, in part, the list of potential ligands as disclosed by the applicant. See, app. p. 3-4, crossover paragraph. Whichever of groups (A) to (F) (or whatever other molecule type) the Applicant elects, the applicant is also required to specify a specific compound, and if the Applicant elects any of groups (A) to (C) the Applicant is required to elect a specific sequence (e.g. pick one embodiment of the sequence in claim 15).

The inventions are distinct, each from the others, for the following reasons:

3. Inventions (A)-(F) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as usable together, and each relates to a prion ligand of a different chemical structure, each of which has different mechanics of binding to the prion protein. Because different molecule types and different modes of binding are present, and because the ligands are not disclosed as usable together, the inventions are distinct.

4. Inventions II and III, and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions all relate to different methods of using the same product. Each of the methods performs a different function- the detection of a prion, isolating a prion, and treating prion-associated pathologies. Each of these different types of functions achieves a different effect. As the methods have different purposes, and are not disclosed as usable together, they constitute distinct inventions.

5. Inventions I, and II-IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention I (the prion ligand) is capable of use in several materially different processes (those of Inventions II –IV). Because each of the different processes is materially different from the others for the reasons stated above, and because the product is used in all of them, the product is usable in several materially different processes, and is thus distinct from them.

6. Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product is a ligand to prion proteins, and the process is a method of identifying such ligands by running an assay of potential ligands against D-amino acids of a prion protein sequence. However, the ligands to the prion proteins could also be identified through other methods; for example, the ligands could be identified by detecting in vitro prion inhibition by test agents. Because the ligands may be identified by multiple methods, the method of making in this case is a distinct invention from the product made.

7. Inventions I, II-IV, and V are related as product, process of using, and process of making. Inventions in this relationship can be shown to be distinct if the product can be shown to be distinct from both the process of using and the process of making (MPEP 806.05(i)). As is shown

above, the product claims have been shown to be distinct from both the process of making the product and the process of using it. See ¶¶ 6, 7 above. For those reasons, the product, process of making, and process of using inventions in this application are distinct.

*Examiner's Notes*

The Examiner has noted some problems with the claims that he requests the applicant address in the reply to this restriction.

8. In Claim 40, the applicant refers to "said peptide" in describing the formation of a complex between the "ligand of claim 1" and a prion protein. There is no antecedent basis for the "said peptide." While peptides are included in the ligands of claim 1, they are not the only ligand compounds covered by the claim. Thus, the combination of "said peptide" and the breadth of claim 1, make the current reading of claim 40 indefinite.

9. In claim 17, the applicant refers to Table 1. It is generally preferred that claims not refer to the specification unless it is necessary to do so, further, by referring to the claim, the applicant has indicated that the control included in the table are included within the claim. Because the controls are not identified in the claim, and are not disclosed as part of the invention, patentability problems may arise due to the reference to the Table. In this case, the presumptively intended claim boundaries would be achieved through use of the SEQ ID No's, rather than reference to the Table.

*Conclusion*

10. Because these inventions are distinct for the reasons given above, because the literature and sequence searches required for any one of the groups is not required for the others, and

because the inventions have divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

11. Applicant is advised that in order for the reply to this requirement to be complete, it must include an election of an invention to be examined as described above, even if the requirement is traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the

rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas  
Patent Examiner  
March 27, 2002

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